1624 $A
#19
10/4/01

Practitioner's Docket No. U 011904-5 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: VIDYA BRAJ **LOHRAY**, et al
Serial No.: 09/179,002 Group No.: 1624
Filed: OCTOBER 26, 1998 Examiner: RAYMOND, R.
For: NOVEL HETEROCYCLIC COMPOUNDS AND THEIR USE IN MEDICINE, PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM

Assistant Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 C.F.R. 1.97(c))

NOTE: An information disclosure statement shall be considered by the Office if filed . . . before the mailing date of either (1) a final action under § 1.113 or (2) a notice of allowance under § 1.311, whichever occurs first, provided the statement is accompanied by either a statement as specified in paragraph (e) of section 1.97 or the fee set forth in § 1.17(p).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

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NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final. Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed ***after*** three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but ***before*** the mailing date of either:

   (1) a final action under § 1.113 or
   (2) a notice of allowance under § 1.311,

   whichever occurs first.

STATEMENT OR FEE

2. Accompanying this transmittal is
   (check either A or B below)

A. [ ] a statement as specified in 37 C.F.R. 1.97(e).

OR

B. [✓] the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement under § 1.97(c). ($180.00).

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[ ] Charge Account No. _____ in the amount of $ _____.
A duplicate of this request is attached.

If any additional fees are due, please charge Account 12-0425.

SIGNATURE OF PRACTITIONER

Reg. No. 33,778

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: VIDYA BRAJ **LOHRAY**, et al

Serial No.: 09/179,002 Group No.: 1624

Filed: OCTOBER 26, 1998 Examiner.: RAYMOND, R.

For: NOVEL HETEROCYCLIC COMPOUNDS AND THEIR USE IN MEDICINE, PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM

Attorney Docket No.: U 011904-5

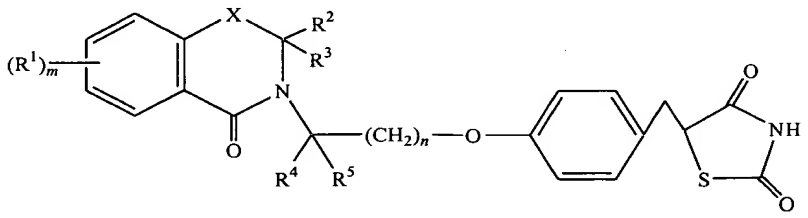
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

We draw the attention of the Examiner to the attached references which are also listed on the attached Form PTO-1449.

U.S. Patent 5,710,152 issued January 20, 1998 to SS Pharmaceutical Co., Ltd. This patent discloses a benzoazine derivative of the formula:



CERTIFICATE OF MAILING (37 CFR 1.8a)

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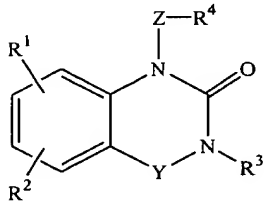
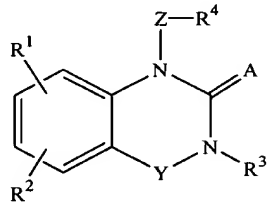
Date: September 26, 2001

(Signature of person mailing paper)

These compounds include a 2,4-thiazolidinedione group. According to SSP, the compound exhibits superior effects for reducing blood glucose value, plasma insulin value, and plasma triglyceride value, and is useful as a medicament for preventing or treating diabetes, hyperlipidemia, and obesity.

U.S. Patents 4,734,419 issued March 29, 1988 and 4,883,800 issued November 28, 1989 both to Fujisawa Pharmaceutical Co., Ltd. These patents disclose compounds of the formula:

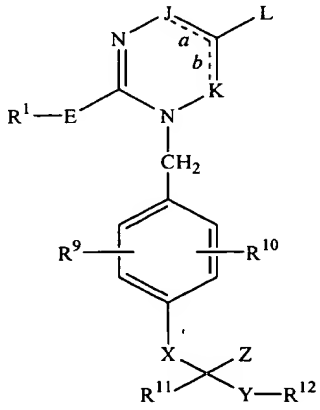




where Z is lower alkylene and R^4 is carboxy or protected carboxy, R^3 is phenyl (lower) alkyl which may have one or more substituent(s) selected from the group consisting of halogen, lower alkoxy, halo (lower) alkyl and lower alkyl.

The compounds are disclosed as having aldose reductase-inhibitory activity.

U.S. Patent 5,420,133 issued on May 20, 1995 to Merck & Co., Inc., and discloses phenoxyphenylacetic acid of the formula:



where

J is (a) –C(=M)– , (b) J and L are connected together to form a 6-membered aromatic ring substituted with R^{7a}, R^{7b}, R^{8a}, and R^{8b}, or (c) J and L are connected together to form a 6-membered aromatic ring containing one nitrogen atom not at J^1, substituted with R^{7a}, R^{7b}, R^{8a}, and R^{8b}; R^{7a}, R^{7b}, R^{8a}, and R^{8b} may be hydrogen;

K is (a) –C(=M)–, (b) K and L are connected together to form a 6-membered aromatic ring substituted with R^{7a}, R^{7b}, R^{8a}, and R^{8b}, or (c) K and L are connected together to form a 6-membered aromatic ring containing one nitrogen atom, substituted on the carbon atoms with R^{7a}, R^{7b} and R^{8b}; and one of a or b is a double bond in the compound provided that when J is –C(=M)– then b is a double bond and when K is –C(=M)– then a is a double bond;

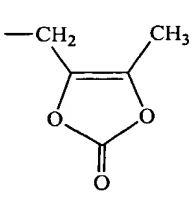
L is the point of attachment of the 6-membered fused aromatic ring optionally containing one nitrogen atom;

X is a single bond;

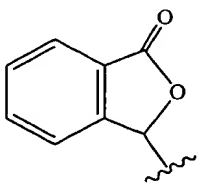
Z may be (a) $–CO_2H$ or (b) $–CO_2R^{19}$;

R^{19} is (a) $(C_1–C_4)$–alkyl,(b) $CHR^{20}–O–COR^{21}$, (c) $CH_2CH_2–N[(C_1–C_2)–alkyl]_2$, (d) $CH_2CH_2–N[CH_2CH_2]_2O$, (e) $(CH_2CH_2O)_y–O–[(C_1–C_4)–alkyl]$, wherein y is 1 or 2, (f) aryl or

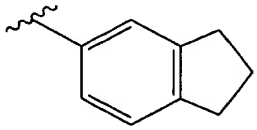
CH_2–aryl, where aryl is phenyl or naphthyl or optionally substituted with $CO_2(C_1–C_4)$–alkyl,



(g)

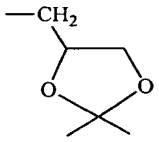


(h)



(i)

or



R^{11} and R^{12} are independently: (a) H, (b) $(C_1–C_6)$–alkyl, unsubstituted or substituted with a substituent selected from the group consisting of: (i) aryl, (ii) $(C_3–C_7)$–cycloalkyl, (iii) NR^2R^{21}, (iv) morpholin-4-yl, (v) OH, (vi) CO_2R^{2a}, or (vii) $CON(R^2)_2$, (c) aryl or

aryl–(C_1–C_2)–alkyl, unsubstituted or substituted with 1 to 3 substituents selected from the group consisting of : (i) Cl, Br, I, F, (ii) (C_1–C_6)–alkyl, (iii) [(C_1–C_5)–alkenyl]CH_2–, (iv) [(C_1–C_5)–alkynyl]CH_2–, (v) (C_1–C_6)–alkyl–$S(O)_n$–$(CH_2)_n$–, (vi) –CF_3, (vii) –CO_2R^{2a}, (viii) –OH, (ix) –NR^2R^{16}, (x) –NO_2, (xi) –NR^2COR^2, (xii) –$CON(R^2)_2$, (xiii) –G–[(C_1–C_6)–alkyl]–R^{18}, (xiv) –$N[CH_2CH_2]_2Q$, or (xv) –$P(O)[O–(C_1–C_4)–alkyl]_2$, and can additionally be substituted with 1 or 2 substituents selected from the group consisting of: Br, Cl or F, (d) (C_3–C_7)–cycloalkyl, or (e) when Y is single bond, R^{11} and R^{12} can be joined to form a ring of 5 to 7 carbon atoms, the ring can be benzo-fused and one carbon of which can be replaced with a heteroatom selected from the group consisting of: O, $S(O)_n$ or NR^{17};

Y is (a) single bond, (b) –O–, (c) –$S(O)_n$–, or (d) –NR^{13}–; and except that X and Y are not defined in such a way that the carbon atom to which Z is attached also simultaneously is bonded to two heteroatoms (O, N, S, SO, SO_2);

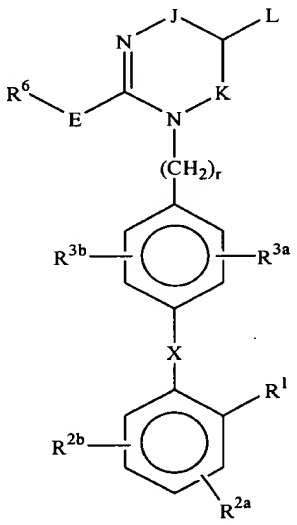
E is (a) a single bond, (b) –$S(O)_n(CH_2)_s$–, or (c) –O–; and n is 0 to 2; and s is 0 to 5;

R^1 is (a) (C_1–C_6)–alkyl, (C_2–C_6)–alkenyl or (C_2–C_6)–alkynyl each of which is unsubstituted or substituted with a substituent selected from the group consisting of: (i) aryl as defined below, (ii) (C_3–C_7)–cycloalkyl, (iii) Cl, Br, I, F, (iv) OH, (v) NH_2, (vi) $NH(C_1–C_4)$–alkyl, (vii) $N[(C_1–C_4)–alkyl]_2$, (viii) $NHSO_2R^2$, (ix) CF_3, (x) $COOR^2$, or (xi) SO_2NHR^{2a}; and (b) aryl, wherein aryl is defined as phenyl or naphthyl unsubstituted or substituted with 1 or 2 substituents selected from the group consisting of (i) Br, I, Cl, F, (ii) (C_1–C_4)–alkyl, (iii) (C_1–C_4)–alkoxy, (iv) NO_2, (v) CF_3, (vi) $SO_2NR^{2a}R^{2a}$, (vii) (C_1–C_4)–alkylthio, (viii) hydroxy, (ix) amino, (x) (C_3–C_7)–cycloalkyl, (xi) (C_3–C_{10})–alkenyl; and (c) heteroaryl, wherein heteroaryl is defined as unsubstituted, monosubstituted or disubstituted heteroaromatic 5– or 6–membered cyclic moiety, which can contain one or two members selected from the group consisting of N, O, S, and wherein the substituents are

members selected from the group consisting of: (i) Cl, Br, I, or F, (ii) OH, (iii) SH, (iv) NO_2, (v) $(C_1–C_4)$–alkyl, (vi) $(C_2–C_4)$–alkenyl, (vii) $(C_2–C_4)$–alkynyl, (viii) $(C_1–C_4)$–alkoxy, or (ix) CF_3, or (d) $(C_1–C_4)$–perfluoroalkyl.

The corresponding application in the UK is GB2277446.

European Patent Application EP 0411766A1 filed on June 29, 1990 and U.S. Patent 5,240,928 issued on August 31, 1993 to Merck & Co., Inc., disclose phenoxyphenylacetic acid of the formula:



wherein

J is –C(=M)– or J and L are connected together to form a 6 carbon aromatic ring substituted with R^{7a}, R^{7b}, R^{8a}, and R^{8b}, provided that only one of J and K is –C(=M)–;

X is a single bond;

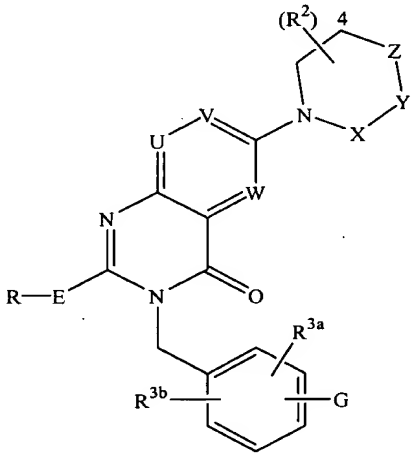
L is connected with J or K to form an aromatic ring as defined above;

E is a single bond, $–NR^{13}(CH_2)_s–$, $–S(O)_x(CH_2)_s–$ where x is 0 to 2 and s is 0 to 5, –CH(OH)–, –O–, or CO–;

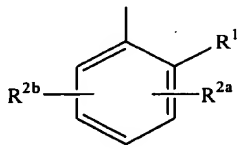
R^6 is (a) aryl phenyl or naphthyl optionally substituted with 1 or 2 substituents selected from the group consisting of halo (Cl, Br, I, F) O–$C_1–C_4$–alkyl, $C_1–C_4$–alkyl, $–NO_2$,

$-CF_3$, $-SO_2NR^9R^{10}$, $-S-C_1-C_4$–alkyl, –OH, $-NH_2$, C_3-C_7–cycloalkyl, C_3-C_{10}–alkenyl; (b) straight chain or branched C_1-C_6–alkyl, C_2-C_5–alkenyl or C_2-C_5–alkynyl each of which can be optionally substituted with a substituent with a substituent selected from the group consisting of aryl as defined above, C_3-C_7 cycloalkyl, halo (Cl, Br, I, F), CF_3, CF_2CF_3, $-NH_2$, $NH(C_1-C_4$–alkyl), $-OR^4$ $-N(C_1-C_4$–alkyl$)_2$, $-NH-SO_2R^4$, $-COOR^4$, and $-SO_2NHR^9$; or (c) an unsubstituted, monosubstituted or disubstituted heteroaromatic 5 or 6 membered cyclic ring which can contain one or two members selected from the group consisting of N, O, S, and wherein the substituents are members selected from the group consisting of –OH, –SH, C_1-C_4–alkyl, C_1-C_4–alkoxy, $-CF_3$, halo (Cl, Br, I, F), or NO_2; (d) C_3-C_7–cycloalkyl; (e) perfluoro–C_1-C_4–alkyl; or (f) H.

European Patent Application 0534706A1 filed on September 22, 1992 by Merck & Co., Inc. discloses a compound of the formula:



wherein G is (1) R^1 or



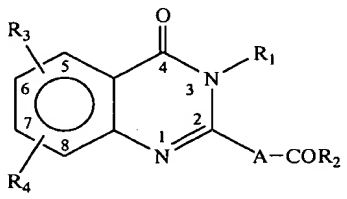
X is 0, 1, or 2, and s is 0-5, or (6) $-NR^3(CH_2)_s-$ where R^3 is (a) –H, (b) C_{2-4} alkanoyl, (c) C_{1-6} alkyl, (d) C_{2-6} alkenyl, (e) C_{3-7} cycloalkyl, (f) phenyl, or (g) benzyl;

R is (1) aryl, (2) heteroaryl, (3) C_{3-7} cycloalkyl, (4) polyfluoro–C_{1-4} alkyl, (5) –H, (6) C_{2-6} alkenyl, (7) C_{2-6} alkynyl, (8) C_{1-6} alkyl, either unsubstituted or substituted with: (a) aryl, (b) C_{3-7} cycloalkyl, (c) halo, (d) $-NH_2$, (e) $-NH(C_{1-4}$ alkyl), (f) $-N(C_{1-4}$ alkyl$)_2$, (g) $-OR^4$, wherein R^4 is (i) –H, (ii) aryl, (iii) heteroaryl, (iv) C_{1-6} alkyl, (v) aryl–C_{1-6} alkyl or (vi) C_{3-7} cycloalkyl; (h) $-COOR^4$, (i) $-NHSO_2R^4$, or (j) $-SO_2NHR^5$, wherein R^5 is (i) –H, (ii) C_{1-5} alkyl, (iii) aryl or, (iv) $-CH_2-$aryl;

U, V and W are independently –CH= or –N= provided no more than one of U, V and W is –N= at one time.

These compounds are disclosed as having endothelin antagonist activity and therefore useful in treating cardiovascular disorders.

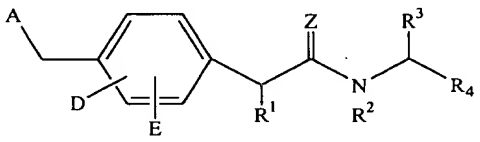
U.S. Patent 4,183,931 issued January 15, 1980 to Research Corporation discloses 2-ketoalkyl-4(3H)-quinazolinones of the formula:



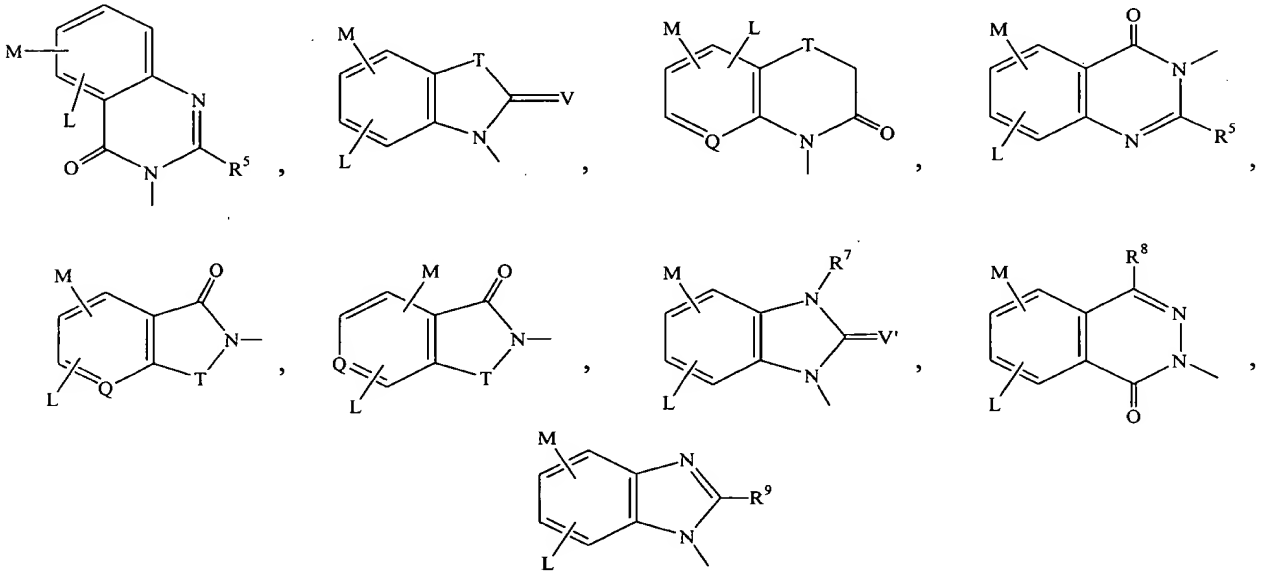
wherein R_1 is an aliphatic, cycloaliphatic or hydrocarbon aromatic group of 1-10 carbon atoms; A is divalent alkylene of 1 to 10 carbon atoms; and R_2 is an aliphatic, cycloaliphatic, hydrocarbon aromatic or heterocyclic group of 1-10 carbon atoms formed by condensing an acyl ester of the formula R_2COOR' which can be dissociated to form $-COR_2$ and R'OH in which R' is the alcoholic portion of said ester. However, this patent does not disclose a phenyl group between an alkylene or alkeneoxy group and the COR_2 group. The compounds

are disclosed as having activity as CNS depressants and anticonvulsants.

U.S. Patent 5,811,429 issued on September 22, 1998 to Bayer Aktiengesellschaft and discloses a compound of the formula:



wherein A represents a radical of the formula:



T denotes a group of the formula $-SO_2$ or –CO or an oxygen or sulphur atom;

V denotes an oxygen or sulphur atom;

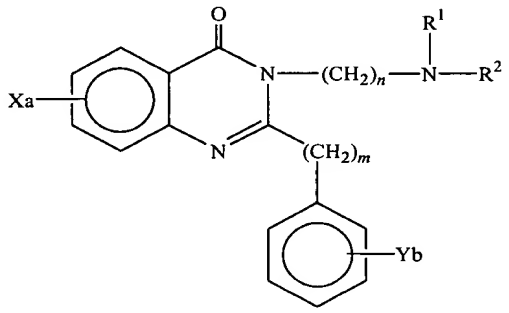
R^9 denotes trifluoromethyl, benzyl or a 5- to 7-membered, optionally benzo-fused heterocyclic radical having up to 3 heteroatoms from the series consisting of S, N and/or O, which is optionally substituted up to 3 times in an identical or different manner by halogen, phenyl, hydroxyl or by straight-chain or branched alkyl or alkoxy having in each case up to 4 carbon atoms, or denotes a group of the formula $-S(O)_a-R^{10}$, wherein *a* denotes the number 0, 1 or 2;

R^5 may represent an optionally substituted straight-chain or branched alkyl having up to 6 carbon atoms. The right-hand side of the structure includes Z which represents oxygen and sulfur and includes a nitrogen atom in the chain.

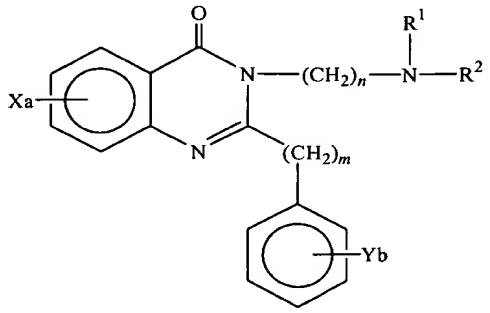
The Examiner's attention is drawn to compounds LVI, LXI, LXII, LXIII and LXIV in Table IV and compounds C, CI and CII in Table V.

The compounds are disclosed as having anti-atherosclerotic action.

U.S. Patent 4,668,682 issued May 26, 1987 to Mitsubishi Chemical Industries Limited and discloses 2-phenylalkyl-3-aminoalkyl-4(3H)-quinazolone compound of formula I:



European Patent Application 0169 537 filed July 23, 1985 by Mitsubishi Yuka Pharmaceutical Co., Ltd. discloses compounds of the formula:



where

Y represents an alkyl group having 1 to 5 carbon atoms, an alkoxy group having 1 to 5 carbon atoms, a benzyloxy group, a halogen atom or a nitro group and b is independently an integer of 1 to 3. The compounds have calcium antagonistic, vasodilative and

antihypertensive activities.

Respectfully submitted,

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